UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CYNTHIA CAMP AND BRIAN CAMP Plaintiffs, v. EXACTECH, INC. and EXACTECH U.S., INC; Defendants.	Civil Action No.: COMPLAINT & DEMAND FOR JURY TRIAL

NOW COMES Plaintiffs CYNTHIA CAMP AND BRIAN CAMP (Plaintiffs), by and through the undersigned attorneys, and bring this action against EXACTECH, INC. ("EXACTECH") and EXACTECH US, INC. ("EXACTECH US") (hereafter collectively as "Defendants or Exactech"), for personal injuries suffered as a proximate result of the implantation of the Connexion GXL Liner within the Novation Crown Cup Cluster-Hole Shell ("The Device") and allege upon information and belief as follows:

I. PARTIES, JURISDICTION, VENUE

1. This is a lawsuit involving unreasonably dangerous hip implant components designed, marketed, manufactured, and sold by Defendants, where such components caused injury to Plaintiff. The particular components at issue in this lawsuit are the "Connexion GXL Hip Liner" and Novation Crown Cup Liners (hereinafter, these products may be referred to as "GXL" or "GXL Liner") which was sold as part of the Novation, Acumatch, and MCS Hip Systems.

2. At all times relevant to this complaint, Plaintiffs CYNTHIA CAMP AND BRIAN CAMP were residents of Mount Laurel, New Jersey.

3. Defendant, EXACTECH, INC. is a Florida corporation with its principal place of business at 2320 NW 66th Street, Gainesville, Florida 32653.

4. Defendant EXACTECH U.S., INC. is a Florida corporation with its principal place of business at 2320 NW 66th Street, Gainesville, Florida.

5. At all relevant times, Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold hip implant systems in Philadelphia, Pennsylvania and throughout the United States.

6. At all times relevant to this action, Defendant EXACTECH INC. was and is registered to do business in the State of Pennsylvania, with Entity Number 1051382.

7. At all times relevant to this action, Defendant EXACTECH U.S. INC. was and is registered to do business in the State of Pennsylvania, with Entity Number 4161924.

8. At all times relevant to this action, Defendants received substantial revenue from goods used or consumed, or services rendered, in the State of Pennsylvania, including Philadelphia County

9. At all relevant times, Defendants were in the business of, and profited from, the design, manufacture, marketing, distribution and/or sale of medical devices, including the hip implants which was implanted in Plaintiff CYNTHIA CAMP.

10. At all relevant times, Defendants were responsible for placing the medical devices implanted into Plaintiffs into the stream of commerce and advertised, marketed, sold and/or distributed such products either directly or indirectly to members of the general public, including Plaintiff.

11. Jurisdiction and venue are proper in the Eastern District of Pennsylvania because Defendants are all corporations organized under the laws of the State of Florida and Plaintiffs are New Jersey citizens and a substantial portion of the tortious

conduct alleged in this Complaint took place within the Eastern District of Pennsylvania where Plaintiff CYNTHIA CAMP had her hip implantation surgeries.

12. Jurisdiction and venue are proper in the Eastern District of Pennsylvania because Defendants are all corporations registered to do business in the State of Pennsylvania.

13. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds Seventy-Five Thousand Dollars ($75,000.00), exclusive of interest and costs, and because there is complete diversity of citizenship between the Plaintiff and all Defendants.

II. SPECIFIC FACTUAL ALLEGATIONS

14. On or about April 19, 2013, Plaintiff CYNTHIA G. CAMP underwent a right total hip replacement surgery and was implanted with a Novation Crown Cup Cluster-Hole acetabular shell, a Novation Neutral Liner Crown Cup Group 1, (Connexion GXL) polyethylene liner (reference number 130-28-51, lot number 1581745), a Novation Press-Fit Femoral Stem, Tapered and a CoCr femoral head 28 mm. Plaintiff's hip replacement surgery was performed at Hahnemann University Hospital on Broad and Vine Streets in Philadelphia, PA.

15. Plaintiff began feeling pain and discomfort and returned to her orthopedist at Hahnemann University Hospital for evaluation.

16. On or about December 16, 2016, a CT scan revealed "some liner wear within the acetabulum" and "evidence of osteolysis along the superior aspect of the acetabulum."

17. The pain progressed and records reflect that by April of 2017 the pain evolved to the point where CYNTHIA CAMP was in so much pain that she was not "able to go to work or sleep."

18. On or about June 8, 2017, Plaintiff CYNTHIA G. CAMP underwent painful and risky right total hip replacement revision surgery at Hahnemann University Hospital to remove the defective GXL liner due to "Eccentric poly[ethylene] wear." Her GXL liner and femoral head were removed and she was implanted with a new Novation Crown Cup size 28 neutral Connexion GXL liner and size 28 mm +0 femoral head.

19. On or about October 3, 2017, Plaintiff CYNTHIA G. CAMP suffered a dislocation of her right total hip replacement. She was treated with a closed reduction on or about October 4, 2017.

20. On June 29, 2021, Defendant EXACTECH INC. initiated a Class 2 Recall of the defective GXL liner.

21. Due to right groin pain at rest and with activity, CYNTHIA CAMP returned to her orthopedic surgeon for evaluation.

On or about September 21, 2021, x-rays showed "abnormal superior wear of [her] polyethylene" liner and "evidence of osteolysis in the ischium and ilium." Her implanting orthopedist determined she would need revision surgery given the "extensive polyethylene wear and osteolysis." Repeat x-rays on or about September 27, 2021 revealed an "almost completely worn-out liner and significant osteolysis behind the cup."

22. Osteolysis is a progressive condition where bone is destroyed.

23. On or about November 2, 2021, her implanting orthopedist observed her September 30, 2021 CT scan demonstrated "extensive osteolysis with significant destruction of the posterior column" and again discussed revision surgery though "Because of the history of 2 successive failures of the polyethylene within 4 years," her implanting orthopedist indicated he "would need to be satisfied that changes have been made and the quality of the polyethylene that would give a longer functional capability than 4 years."

24. On or about December 8, 2021, the surgeon who would perform her 2021 revision surgery discussed her need for revision surgery as the component "was recalled and is the culprit for her early osteolysis and poly[ethylene] breakdown."

25. On or about December 14, 2021, Plaintiff CYNTHIA G. CAMP underwent a second painful and risky revision surgery at Shore Medical Center in Somers Point, NJ. Her polyethylene liner was removed and found to be "significantly worn." She was found to have "bone defects." Cysts which "seemed to constitute most of [the] superior acetabulum." The cysts were full of a "chalky white granular substance."

26. Plaintiff CYNTHIA G. CAMP has endured and continues to endure a painful recovery and rehabilitation process from her revision surgery.

27. Plaintiff CYNTHIA CAMP continues to endure painful recovery and rehabilitation process from her revision surgeries and was forced to retire early.

28. Plaintiff sustained injuries caused by the latent effects of exposure to polyethylene and the resins used to process the polyethylene and the degradation byproducts of those toxic materials.

29. A comparison of muscle tissue from patients implanted with ceramic liners versus polyethylene liners during total hip arthroplasty demonstrated decreased osteolysis and capsule atrophy as well as less structural change to the muscles. *See* Hernigou, Phillippe *et al.*, "Ceramic-on-ceramic THA Associated With Fewer

Dislocations and Less Muscle Degeneration by Preserving Muscle Progenitors," *Clin Orthop Relat Res* (2015) 473:3762-3769.

30. Plaintiff exhibited due diligence but could not have reasonably discovered the cause of her hip failures and the connection between her injuries and the conduct of the EXACTECH defendants in producing a defective prosthesis with its prematurely failing polyethylene liner until after the recall in 2021 when she returned for treatment of her pain.

III. GENERAL FACTUAL ALLEGATIONS

A. Total hip arthroplasty using UHMWPE plastic is common and highly successful.

31. Total Hip Arthroplasty (hereafter "THA") is the term used to describe surgery wherein a patient's natural hip anatomy is replaced with synthetic components. THA is also commonly referred to as "hip replacement surgery." A patient may need a THA for a variety of medical reasons. For example, arthritis may damage the normally smooth cartilage on the femoral head and motion against the damaged cartilage leads to pain.

32. A synthetic hip replacement system implanted during a THA procedure generally has four main components: 1) Acetabular shell; 2) Acetabular liner; 3) Femoral head; and 4) Femoral stem. Figure 1 and Figure 2 below graphically represent these typical

components as well as how these components are situated in the body once implanted:

Figure 1

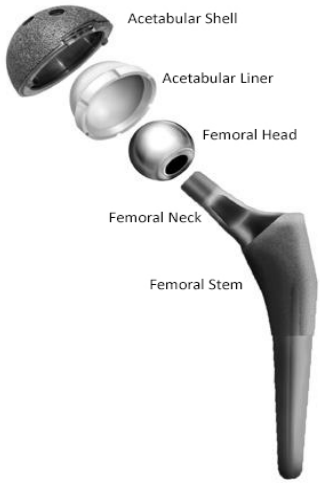

Figure 2

33. The materials used in a hip replacement are very important in determining the outcome of the implant. There are many possible combinations of materials used which can lead to very different clinical success rates.

34. In the 1960s, Sir John Charnley set the standard for today's hip replacement systems by utilizing acetabular liners made of ultra high molecular weight polyethylene ("UHMWPE"). This plastic material family remains the material of choice as the predominant bearing surface in total join replacements today.

35. The original UHMWPE implants utilized by Sir John Charnley in the 1960s had 20-year survivorship rates as high as 90%. [1] [2]

36. Approximately 400,000 hip replacements are performed annually in the United States today and this number is expected to increase to 635,000 by 2030.[3]

37. The great majority of these hip replacements utilize a metal acetabular cup, a plastic/polyethylene acetabular liner, a metal or ceramic femoral head, and a metal femoral stem. Further, almost all of the plastic acetabular liners belong to the UHMWPE lineage of plastics, first introduced by Charnley in the 1960s.

B. Despite unparalleled success, early UHMWPE had challenges due to primitive packaging technology and due to concerns of wear over the long-term.

38. Despite relative success utilizing UHMWPE components, the orthopedic industry recognized room for improvement.

39. In the 1980s, the orthopedic industry recognized that UHMWPE which were sterilized with gamma radiation *and* packaged in air would be subject to oxidation and a degradation of the material

[1] Neuman L, Freund KG, Sorenson KH, 'Long Term Results of Charnley Total Hip Replacement' J Bone and Joint (British) 76B:245-251(1994)

[2] Wroblewski BM, 'Charnley Low Friction Arthroplasty of the Hip. Long Term Results' Clin Ortho Rel Res 292:191-201(1993)

[3] Sloan M, Premkumar A, SM, Sheth NP, 'Projected Volume of Primary Total Joint Arthroplasty in the US 2014 to 2030' J Bone Joint Surg 100:1455(2019)

properties of the UHMWPE components. This caused delamination, pitting, fracture and breakage of the components, and a host of related negative clinical outcomes in patients.

40. Also in the 1980s, it became evident that UHMWPE liners generated polyethylene particles in clinical use. *Over the long term*, those particles can cause a biological response termed osteolysis. Osteolysis is a process which makes bone weak or even disappear. As a result of osteolysis the patient experiences pain, the implant may loosen, and revision surgery is required. Despite the success of the early generation of UHMWPE devices over early and mid-terms, excessive wear generation ultimately limited the *long-term* success of generation of implants.

C. UHMWPE plastic utilized in hip replacements has improved since the 1980s.

41. In the 1990s, the orthopedic industry pursued improvements in the material properties as well as the packing and sterilization methods utilized for UHMWPE implants.

42. By the late 1990s most manufacturers in the orthopedic industry had addressed the issue of oxidation with changes in the packaging and sterilization process, including but not limited to:

a) Sterilization in vacuum sealed packaging;
b) Sterilization using inert gas instead of oxygen; and
c) Gas Plasma Sterilization.

43. As a result of advancements in the packaging and sterilization methods in the 1990s, the rate of problems associated with oxidation of UHMWPE had been greatly reduced.

44. There were also several attempts of improving the wear rates of UHMWPE which generally involved doses of irradiation and post irradiation treatments.

45. One of the ways in which the wear rate of polyethylene was improved by a process called "cross linking." In this process, the UHMWPE was exposed to certain levels of either gamma or electron beam irradiation.

46. Highly CrossLinked Ultra High Molecular Weight Polyethylene ("XLPE") is stronger, harder, and reduces the amount of plastic wear produced during articulation of components as compared with UHMWPE.

47. If using gamma radiation, crosslinking of UHMWPE requires that UHMWPE be exposed to gamma radiation in the range of 50-100kGy.

48. By the mid 2000s, it became clear that XLPE components had superior clinical performance to UHMWPE as well as the alternative attempts to improve UHMWPE. XLPE implants have less than half the revision rate of UHMWPE implants. Accordingly, the industry standard shifted to utilization of XLPE for acetabular liners.

49. By 2004, UHMWPE and XLPE components were so successful that they were utilized in 90% of *all* hip replacements. [4]

50. Further, in the mid-2000s, an increasing number of orthopedic manufacturers utilized Vitamin E in their XLPE to further improve the long-term wear properties of the implants.[5] The main purpose was to prevent oxidative degradation of the plastic and lower the osteolytic potential of these implants.

51. XLPE and Vitamin E infused XLPE implants, in use since the late 1990s and mid 2000s, have greatly improved the long-term durability, wear resistance, and clinical outcomes with the already successful UHMWPE implants originally introduced in the 1960s.

52. These advancements allow for polyethylene components in hip implants to last 20+ years in a patient.

D. Defendants, like many implant manufacturers, sold UMHWPE implants in the 1990s and 2000s.

53. Defendants have marketed a number of hip implants utilizing liners in the UHMWPE family of plastics.

[4] Kurtz SM. The UHMWPE Handbook: Ultra-High Molecular Weight Polyethylene in Total Joint Replacement. New York, NY: Academic Press; 2004.

[5] Gigante A, Bottegoni C, Ragone V, Banci L. Effectiveness of Vitamin-E-Doped Polyethylene in Joint Replacement: A Literature Review. *J Funct Biomater*. 2015;6(3):889-900. Published 2015 Sep 8. doi:10.3390/jfb6030889.

54. In 1992 and 1999, respectively, Defendants began marketing the MCS[6] and AcuMatch A-Series[7] hip implants, each with a UHMWPE liner.

55. In 2004, Defendants sought clearance from the FDA to sell additional size options for both the MCS and A-Series hip systems. [8] Other than providing these new size options, the Defendants claimed that these new sizes were "substantially equivalent" to the previous sizes "in design, materials of construction, manufacturing, and other characteristics."

56. Each of these AcuMatch and MCS hip systems cleared for sale in 1992, 1999, and 2004 represents a traditional metal on plastic hip system utilizing UHMWPE as the material for the liner component.

E. Defendants began to market "enhanced" UHMWPE in the mid-2000s with the promise of reduced wear and increased longevity.

57. Beginning in 2005, Defendants began to market a new generation of "enhanced" polyethylene products.

58. This generation of products included the GXL acetabular liners with "enhanced" polyethylene for use in a variety of hip systems. They called this product "moderately cross-linked."

[6] K921114 Summary of Safety and Effectiveness
[7] K993082 Summary of Safety and Effectiveness
[8] K040613 Summary of Safety and Effectiveness

59. In 2005 Defendants marketed their AcuMatch A-Series "Connexion GXL Enhanced UHMWPE Acetabular Liner."[9] Further, in 2007, Defendants marketed their Novation Crown Cup and Liners, which they claimed also utilized "enhanced" GXL liners.[10]

60. To purportedly "enhance" the standard UHMWPE that Defendants had been using in their previous liners, Defendants exposed the GXL liners to two treatments of gamma radiation at 25kGy for each treatment. This two step and level of gamma radiation is different from and lower than radiation doses traditionally used.

61. Defendants claimed that these purportedly "enhanced" GXL liners were "developed to create a robust arthroplasty respecting the need for lower wear, sufficient fracture toughness, and oxidation behavior to provide a lifelong implant for patients." [11]

62. Gary Miller, PhD, the co-founder of Exactech boasted to surgeons in a publication dated March 14, 2017 that "Exactech manufactures Connexion GXL polyethylene components with sheet molded UHMWPE using two precision split doses of 25 kGy each in

[9] K051556 Summary of Safety and Effectiveness
[10] K070479 Summary of Safety and Effectiveness
[11] Peterson, M. J., Yassaman, N., Assessing the Long-Term Clinical Performance of Connexion GXL Polyethylene Acetabular Liners in Total Hip Arthroplasty. 2017 Exactech Brochure.

vacuum packaging for a total of approximately 50kGy to create improved cross-link density."[12]

63. Gary Miller, PhD, Exactech co-founder goes on to warrant on behalf of the company that "[t]his process provides a 59% reduction in gravimetric abrasive wear over the clinically successful standard Exactech.[13]

64. Defendants explicitly claimed that "Connexion GXL enhanced polyethylene acetabular liners provide a low wear rate."[14]

65. Defendants explicitly claimed that "Connexion GXL liners are a result of development programs that are advancing bearing surface technology *while focusing on increasing the longevity of total hip prostheses.*" (Emphasis added).[15]

66. Defendants explicitly claimed that the GXL "provides a 59% wear reduction" over what it deemed was their "clinically successful" standard polyethylene liners. [16] [17]

67. These claims were intended to convince the public, including Plaintiffs and Plaintiff's surgeon, that the GXL was not

[12] https://www.exac.com/optimizing-polyethylene-materials-to-the-application/ as of June 10, 2022.

[13] *Id.*

[14] http://www.exac.com/products/hip/acetabular-systems/connexion-gxl, as of May 11, 2008, as available on the Internet Archive.

[15] *Id.*

[16] http://www.exac.com/products/hip/emerging-technologies/connexion-gxl-polyethylene, as of May 25, 2008, as available on The Internet Archive.

[17] Peterson, M. J., Yassaman, N., Assessing the Long-Term Clinical Performance of Connexion GXL Polyethylene Acetabular Liners in Total Hip Arthroplasty. 2017 Exactech Brochure FOR INTERNAL USE ONLY NOT FOR DISTRIBUTION.

only a safe and effective product for hip replacement, but that it was advantageous to products already on the market.

68. Defendants went so far as to tell their sales representatives in a document labelled "For Internal Use Only" that "Connexion GXL acetabular liners were developed to create a polyethylene articular couple that creates a robust arthroplasty respective the need for lower wear, sufficient fracture toughness, and oxidation behavior to provide a **lifelong implant for patients.**" (Emphasis added). (See note 11)

69. In short, defendants were encouraging their sales representative to relay to surgeons that the liners would last for the patient's lifetime, a palpably false and fraudulent claim.

70. In fact, this technology, involving irradiating the polyethylene half before and half after machining as well as not heat treating the polyethylene, distinguished this polyethylene from others on the market. Other differences include that some other branded polyethylene liners are often sterilized by gas plasma as opposed to gamma radiation used with the Connexion GXL liners.[18]

F. Defendants rushed the GXL to market without sufficient testing for safety or efficacy.

[18] Yakkanti, Unexpected Wear of a Uniquely Designed Moderatley Cross-Linked Polyethylene in Total Hip Arthroplasty, The Journal of Arthroplasty, xxx(2022) 1-6 available at doi.org/10.1016/jarth.2022.01.093

71. Defendants rushed their the GXL liner to market without sufficient testing for safety or efficacy.

72. The rush to market was done in pursuit of market share and profits.

73. Defendants received clearance to sell the GXL after an FDA review process that took less than 30 days.

74. Defendants did not perform any clinical testing for safety or efficacy of the GXL prior to marketing.

75. Defendants generally relied on data for other "predicate" products previously on the market to justify the marketing and sale of the GXL prior to launch. These include Defendants' prior standard UHMWPE liners. [19]

76. Defendants did not have any clinical or clinically-relevant laboratory data supporting their claims that the GXL either produced less wear or had better longevity than standard UHMWPE.

77. Defendants failed to adequately test the in-vivo performance of their "enhanced" UHMWPE products, including the GXL.

78. Defendants failed to adequately test for the clinical effects of the wear generated by the Connexion GXL liner, their "enhanced" polyethylene acetabular liner.

[19] K051556 Summary of Safety and Effectiveness

79. Defendants failed to adequately test for the clinical effects of the wear and performance of the Connexion GXL liner when used within the Novation Crown Cup-Cluster-Hole Shell and with the Biolex Delta femoral head.

G. The GXL is defective because it leads to increased wear and early failure.

80. Defendants' claims that the "enhancements" to the polyethylene in the GXL improve wear resistance and longevity are false.

81. In fact the GXL is defective because the exact opposite is true for the "enhanced" polyethylene Defendants utilized in the GXL.

82. In clinical use, the GXL exhibits a higher than expected rate of failure necessitating early revision surgery.

83. The GXL oxidizes rapidly resulting in the vastly heightened polyethylene degradation.

84. The GXL is defective because it leads to excessive wear and early implant failure.

85. The GXL is defective because the gamma radiation process applied to the GXL increases, rather than decreases, the wear produced by the GXL.

86. The GXL is defective because the sterilization process applied to the components increases the risk of fracture and excessive wear with the GXL.

87. The GXL is defective because the GXL is unreasonably likely to undergo oxidation after manufacture and prior to implant. This weakens the implant, greatly increases wear, and leads to early failure.

88. The GXL is defective because it is unreasonably likely to edge load, leading to increased wear and early failure.

89. The excessive wear associated with the GXL leads to adverse clinical effects in patients, including osteolysis, fracture, loosening, and early revisions.

90. The negative clinical outcomes are progressive the longer the device remains in the body.

91. Early intervention to revise failing implants is critical in order to avoid or minimize injury.

H. Defendants knew of problems, but failed to inform plaintiff and the public.

92. Sometime after introduction of their "enhanced" polyethylene products, including the GXL, to the market, Defendants began receiving reports of adverse clinical outcomes due to wear and early revisions.

93. Defendants' competitors' XLPE products, and even Defendants' previous UHMWPE products, performed significantly better clinically than Defendants' "enhanced" UHMWPE products, including the GXL.

94. Surgeons, sales representatives/distributors, tribologists (scientists and engineers who study retrieved implants), notified defendants of adverse clinical outcomes with Defendants "enhanced" polyethylene products, including the GXL.

95. Defendants failed to properly track and analyze these reports.

96. When surgeons reported concerns due to failures due to wear, Defendants responded to surgeons by claiming that their "enhanced" polyethylene products, including specifically the GXL, was performing well and that there was no cause for concern, despite Defendants' knowledge to the contrary.

97. The Safe Medical Devices Act of 1990 requires manufacturers to report to the Food and Drug Administration deaths, serious illnesses and injuries associated with medical devices. Revision surgeries are considered a mandatory reportable concern to The Center for Devices and Radiological Health of the U.S. Food and Drug Administration ("F.D.A.") responsible for issuing Safety Alerts, Public Health Advisories and Notices relative to medical devices.

98. Defendants failed to report deaths, serious illnesses, injuries and revision surgeries involving the GXL to the F.D.A.

99. As the number of failed GXL implants increased, case studies appeared in medical journals reporting the failures due to excess polyethylene wear.

100. Defendants took affirmative efforts to conceal the risk to the public from the excessive wear and early failure of the GXL.

101. Defendants knew, or should have known, of increased wear and early revisions with their "enhanced" polyethylene and the GXL in enough time to have notified Plaintiff, or Plaintiff's surgeon, and the F.D.A. prior to Plaintiff's implant surgery.

102. An article was published in the Journal of Arthroplasty in May, 2020 entitled "Early Polyethylene Failure in a Modern Total Hip Prostheses: A Note of Caution", in which the four authors, affiliated with the University of Florida in Gainesville reported on a retrospective review of their institutional database from January 2009 to June 2019 revealing patients who presented with significant osteolysis in the setting of prior total hip arthroplasty with an Exactech Connexion GXL Liner. They concluded that "[c]onsidering that no identifiable risk factors related to patient demographics or implant position were identified, the Exactech Connexion GXL liner may be prone to a high rate of early failure form wear and severe secondary osteolysis. We recommend close surveillance of patients with this bearing surface."

103. Their finding directly belies the claim of Exactech in the recall notice set forth below which attributes failures to surgical technique, surgical positioning and patient characteristics.

104. Defendants knew, or should have known, of increased wear and early revisions with the GXL in enough time to have notified Plaintiff, or Plaintiff's surgeon, after Plaintiff's implant surgery but before Plaintiff's revision surgery, such that the extent of Plaintiff's injuries due to the wear and erosion of the implant could have been minimized or possibly avoided.

I. Defendants released an XLPE liner as replacement without recalling the the GXL liner.

105. Despite all of the information Defendants received regarding the failures of their "enhanced" polyethylene products, including their GXL liners, Defendants significantly delayed and obfuscated the recall of the GXL.

106. In 2019, Defendants for the first time began selling their "XLE" liners. This was their first XLPE liner. It is also Vitamin E infused.

107. Defendants' competitors have had XLPE liners available since the late 1990s.

108. Defendants' competitors have had Vitamin E infused XLPE liners available since the mid-2000s.

109. Defendants' 2017 marketing literature for the GXL criticized the use of Vitamin E in its competitor products claiming that "antioxidant-treated polymers (vitamin E)" does "not fully eliminate oxidation potential, and the long-term effects on the body are unknown." (See note 12, *supra*)

110. Nevertheless, once Defendant could no longer deny the failure of the GXL, only two years later, they added Vitamin E to their replacement polyethylene liner which is now being used in the revisions of many patients, including Plaintiff.

111. Defendants claim that their XLE is gamma radiated with 100kGy, the maximum acceptable gamma radiation for cross-linking.

112. Defendants claim that the XLE has lower wear propensities than the GXL.

113. Defendants claim that they transitioned GXL liners out of the US market once the XLE was introduced in 2019.

114. Defendants waited more than two years since the GXL was transitioned out of the market and its XLE replacement was sold to first inform its surgeon customers regarding Defendants' observations of premature wear with the GXL.

115. On June 24, 2021, Defendants admitted that they had become aware of "certain conditions that may put certain patients at a higher risk of premature wear of the GXL."

116. On or about June 28, 2021 in a communication To: Surgeons, Hospitals, Health care professionals posted on its website regarding the Exactech Connexion GXL acetabular polyethylene liners, surgeons are informed "of recent observations made by Exactech regarding the clinical performance of the Connexion GXL acetabular liner."

117. In said communication Exactech claims it is their practice "to perform detailed analysis and inform our surgeon customers and patients as soon as possible when such observations are made."

118. Exactech further informs surgeons that "[d]uring the past ~24 months, Exactech has observed that in a small percentage of patients (.118%) who are between 3-6 years from index total hip arthroplasty, the Connexion GXL liner exhibits early linear and volumetric wear. In some of these patients, wear has led to proximal femoral and acetabular osteolysis. This phenomenon appears to occur when the relative implant position of the acetabular and femoral components in either/both the coronal plane and the sagittal plane results in edge loading of the femoral head on the liner. This phenomenon appears to be more common in direct anterior (DA) hip approaches. This phenomenon appears to be more common in patients with higher activity levels[1]."

119. Exactech's recommendation for surgeons is that "Connexion GXL patients who are less than six (6) years from index surgery and who have not been seen in over 12 months return to the office/clinic for a routine clinical exam and x-rays, including standing AP pelvis, cross-table lateral, and sitting/functional lateral. These x-rays will assess the relative alignment of the acetabular and femoral components and should identify edge loading. For patients with edge loading components, early asymmetric polyethylene wear, and early signs of lysis, the surgeon should consider revising the Connexion GXL liner to Exactech's latest generation HXLPE, Vitamin E liner, if possible."

120. Defendants thus recommended that surgeons consider revising failing GXL liners and replacing them with XLE liners, which are fully compatible replacements.

121. In this communication posted on its website Exactech did not acknowledge that they performed a recall in accordance with FDA procedures and instead couched the action as beneficent to minimize to surgeons the gravity of a recall.

122. However, on July 22, 2021 the FDA posted the recall that actually was dated June 29, 2021 and noted that the "Manufacturer Reason for Recall Risk of edge-loading and premature prosthesis wear is possible in a specific subset of patients with certain implant configurations and surgical

implant positioning and that the recall implicated 89,050 liners in circulation within the United States." *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=188088https://.

123. Defendants' delay in informing the public of problems with their GXL liner until a marketable alternative was available displays a conscious disregard for the safety of the public in favor of profit.

124. Defendants' delay in recalling the GXL liner sooner resulted in CYNTHIA CAMP undergoing a revision surgery on June 8, 2017 to remove the first failed polyethylene component, only to be replaced with another defective component that was recalled in 2021.

125. Defendants' pretext of blaming the recall on physician technique and patient activity level also served to blunt the import and significance of the recall.

IV. Fraudulent Concealment

126. Defendants, through its affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's healthcare providers the true and significant risks associated with the Device and its Connexion GXL Liner, claiming any failures were due to surgical technique, positioning or patient characteristics.

127. Following implantation of the Device, Plaintiff and Plaintiff's healthcare providers relied on Defendants' continued representations that the liner had excellent long-term clinical outcomes.

128. Defendants made these representations with knowledge of their falsity given their knowledge of reports of high failure rates.

129. Although clinical evidence demonstrated that Connexion GXL Liners were failing at a rate higher than promoted with instances of excessive revision rates due to device loosening and polyethylene wear, Defendants failed to initiate a recall earlier or issue any communications to healthcare providers that patients should be monitored.

130. Furthermore, earlier disclosure of these failure rates could have impacted the sale of the company to private equity.

131. Had Defendants not actively concealed evidence of growing reports of premature device failures, Plaintiff would have obtained radiological intervention at an earlier time.

132. Such intervention would have led to an earlier diagnosis of bone loss and earlier removal of the Connexion GXL Liner, thereby reducing damage to bone and tissue.

133. Had Defendants not actively concealed evidence of growing reports of premature device failures, Plaintiff could

have avoided the second revision surgery if she had not been implanted during her first revision surgery with the same defective liner component.

134. As a result of Defendants' actions, Plaintiff and Plaintiff's healthcare providers were unaware, and could not have reasonably known or have learned through reasonable diligence, that Plaintiff had been exposed to the risks identified herein, and that those risks were the result of defects in the product due to Defendants' acts, omissions, and misrepresentations.

135. Accordingly, no limitations period ought to accrue until such time as Plaintiff knew or reasonably should have known of some causal connection between Plaintiff being implanted with the Connexion GXL Liner, and the resulting harm later suffered by Plaintiff as a result by reason of Defendants' fraudulent concealment.

136. Additionally, Defendants are equitably estopped from asserting any limitations defense by virtue of their fraudulent concealment and other misconduct as described herein.

137. Further, the limitations period ought to be tolled under principles of equitable tolling.

V. PUNITIVE DAMAGES ALLEGATIONS

138. The acts, conduct, and omissions of Defendants, as alleged throughout this Complaint were willful and malicious.

Defendants committed these acts with a conscious disregard for the rights, health and safety of Plaintiff and other GXL Liner recipients and for the primary purpose of increasing Defendants' profits from the sale and distribution of the GXL Liner. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

139. Prior to the manufacturing, sale, and distribution of the GXL Liner, Defendants knew that said polyethylene liner was in a defective condition as previously described herein and knew that those who were implanted with the prosthesis would experience and did experience severe physical, mental, and emotional injuries. Further, Defendants, through their officers, directors, managers, and agents, knew that the implant presented a substantial and unreasonable risk of harm to the public, including Plaintiff and as such, Defendants unreasonably subjected consumers of said implants to risk of injury or death.

140. Despite its knowledge, Defendants, acting through its officers, directors and managing agents for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to timely remedy the known defects and failed to warn the public, including Plaintiff, of the extreme risk of injury occasioned by said defects inherent in the GXL liner. Defendants and their

agents, officers, and directors intentionally proceeded with the manufacturing, sale, and distribution and marketing of the GXL Liner knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

141. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff, entitling Plaintiff to exemplary damages.

V. CAUSES OF ACTION

Count One -- Negligence

142. Plaintiffs re-allege and incorporate by reference all paragraphs above as if fully stated herein.

143. Prior to Plaintiff's initial hip surgery, and at all times relevant this action, the Exactech Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

144. Prior to, on, and after the dates of Plaintiff's initial hip surgery, and at all times relevant to this action, the Exactech

Defendants had a duty to exercise reasonable care in testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion, advertisement, marketing, distribution and sale of the Device for implantation into consumers, such as Plaintiff, by physicians and surgeons in the United States.

145. Prior to, on, and after the dates of Plaintiff's initial hip surgery, Defendants breached this duty and failed to exercise reasonable care and were grossly negligent and careless in the testing, study, research, design, formulation, manufacture, inspection, labeling, packaging, promotion, advertisement, marketing, distribution and sale of the Device.

146. Following Plaintiff's initial hip surgery, Defendants breached this duty and failed to exercise reasonable care and were grossly negligent and careless in failing to recall the Device.

147. At all times material hereto, the Defendants had actual knowledge, or in the alternative, should have known through the exercise of reasonable and prudent care, of the hazards and dangers associated with the Device.

148. Despite the fact Defendants knew or should have known the Device posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Device for implantation into consumers.

149. Despite the fact Defendants knew or should have known the Device posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Device for implantation into consumers without revising any warning language or issuing an earlier recall.

150. Defendants failed to advise surgeons and patients of the need for regular follow-up beyond the ordinary practices after a total hip implant as to promptly detect polyethylene degradation and osteolytic failure and timely revise the device to prevent or at least minimize bone loss, osteolysis and related injuries.

151. Defendants failed to exercise due care under the circumstances, and their gross negligence and recklessness includes the following acts and omissions:

152. Negligently failing to properly package the polyethylene components of the Device;

153. Negligently failing to select appropriate third-parties to package the polyethylene inserts used in the Device;

154. Negligently failing to properly supervise and monitor the packaging of the polyethylene inserts used in the Device;

155. Negligently failing to properly and thoroughly select the material that would be used in the packaging of the Device;

156. Negligently failing to properly and thoroughly select the materials that would be used in the Device including avoiding

Vitamin E which is universally accepted as an ingredient to minimize oxidation;

157. Negligently failing to properly and adequately test the Device and their attendant parts before releasing the devices to market;

158. Negligently failing to conduct sufficient post-market testing and surveillance of the Device;

159. Negligently failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Device in accordance with good practices;

160. Negligently designing, manufacturing, marketing, advertising, distributing, and selling the Device;

161. Continuing to negligently manufacture, and distribute the Device after the Defendants knew or should have known of their adverse effects and/or the increased early onset failure rates;

162. Negligently designing, manufacturing, marketing, advertising, distributing, and selling the Device to consumers, including Plaintiff, without an adequate warning of the dangerous risks of the Device;

163. Negligently failing to notify and warn the public, including Plaintiff, and surgeons of reported incidents involving injury and the negative health effects attendant to the use of the Device;

164. Negligently misrepresenting the safety of the Device;

165. Negligently failing to provide warnings, instructions or other information that accurately reflected the risks of early failure of the Device;

166. Negligently failing to provide warnings, instructions or other information that accurately reflected the risks of early degradation of the polyethylene substance in the Device;

167. Negligently failing to exercise due care in the advertisement and promotion of the Device;

168. Negligently disseminating information that was inaccurate, false, and misleading, and which failed to communicate accurately or adequately the high early failure rate associated with the implantation of the Device;

169. Aggressively promoting the Device without proper warnings of the risk of early failure or material degradation in the average user;

170. Aggressively promoting the Device even after Defendants knew or should have known of the unreasonable risks from implantation;

171. Negligently failing to warn consumers, doctors, users and patients that the Device would contain polyethylene materials not properly packaged and/or in accordance with Defendants' specifications;

172. Negligently diminishing or hiding the risks associated with the implantation of the Device;

173. Negligently failing to recall the Device at an earlier date; and

174. Negligently violating applicable state and federal laws and regulations; and in all other ways.

175. Defendants knew and/or should have known that it was foreseeable that consumers such as Plaintiff would suffer injuries as a result of Defendants' failure to exercise ordinary care in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, advertising, preparing for use, warning of the risks and dangers of the defective implants, and otherwise distributing the Device.

176. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

177. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

178. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, labeling, sale, and distribution of the Device, Plaintiff was implanted with the Device and was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

179. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

Count Two - Strict Liability Failure To Warn and New Jersey Product Liability Act

180. Plaintiffs re-allege and incorporates by reference all paragraphs above as if fully stated herein.

181. At all times relevant to this action, while Defendants engaged in the business of designing, manufacturing, selling, marketing, promoting, and placing into the stream of commerce the Device, the product contained defects that made it unreasonably

dangerous beyond the expectations of the ordinary consumer, such as Plaintiff, and were unfit for their intended use.

182. The Device reached Plaintiff without substantial change in the condition in which it was designed, developed, promoted, manufactured, and sold.

183. At the time and on the occasions in question, the Device was being properly used for the purpose for which it was intended, and such device was in fact defective, unsafe and unreasonably dangerous.

184. The foreseeable risk of harm from the defects in the GXL could have been reduced or avoided by providing adequate instructions or warnings.

185. At all times relevant to the action, the dangerous propensities of the Device were known to Defendants or were reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their respective product, and not known to ordinary consumers.

186. The Device was defective and unreasonably dangerous in that the labeling was insufficient to warn users of the hazardous conditions posed by said items, including but not limited to its increased propensity to cause osteolysis and other injuries associated with excessive wear of the GXL.

187. The Device was defective due to inadequate, or the absence of, warnings or instructions, including warning stickers, placards, or proper documentation to alert users regarding the hazards posed by the Device.

188. Defendants had a duty to warn, including a continuing post-sale duty to warn, regarding the unreasonable risk of harm associated with the Device, particularly due to the progressive nature of the risk of injury from wear of the GXL liner.

189. Defendants failed to exercise reasonable care to inform Plaintiff, Plaintiff's doctors, and the medical community about dangers regarding the Device.

190. By reason of the foregoing acts, omissions and conduct committed by the Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

191. By reason of the foregoing acts, omissions and conduct committed by Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

192. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in

the design, formulation, testing, manufacture, labeling, sale, and distribution of the Device, Plaintiff was implanted with the Device and was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

193. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

Count Three -- Strict Liability Design and Manufacturing Defect and New Jersey Product Liability Act

194. Plaintiffs re-allege and incorporate by reference all paragraphs above as if fully stated herein.

195. At the time that Defendants designed, manufactured, packaged, promoted, marketed, sold, supplied, distributed and/or serviced the Device, it contained defects that made it unreasonably dangerous beyond the expectations of the ordinary consumer, and were unfit for their intended use.

196. The Device reached Plaintiff without substantial change in the condition in which it was sold.

197. At the time and on the occasions in question, the Device was being properly used for the purpose for which it was intended, and such device was in fact defective, unsafe, and unreasonably dangerous.

198. The Device as tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold by the Exactech Defendants reached Plaintiff without substantial change in its condition.

199. As alleged herein, the Exactech Defendants knew or had reason to know that the Device caused an increased risk of harm to the Plaintiff and other consumers due to the device's propensity to undergo substantial early polyethylene wear, component loosening, and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery in patients.

200. The Device and packaging as designed carried risks that were outweighed by any utility of the design of the device and packaging because when paired together the implant, the Device was dangerous to an extent beyond that which would be contemplated by the ordinary consumer. At no time did Plaintiff have reason to believe that the Device were in a condition not suitable for proper and intended use.

201. The Device and packaging were defective in design and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff, because the foreseeable risks exceeded or outweighed the purported benefits associated with the device.

202. Feasible safer alternative designs providing the same functional purpose were available to the Exactech Defendants at the time the Device was designed and packaged and offered for sale in the market.

203. The design defects of the Device and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when used and operated for the purposes intended by the Exactech Defendants.

204. The design defects of the Device and corresponding packaging presented an unreasonable risk of harm to users and patients exposed to their danger, including Plaintiff, when they were used and operated in a manner that was foreseeable to the Exactech Defendants.

205. Plaintiff could not, by the exercise of reasonable care, have discovered these design defects and perceived its dangers or avoided injury.

206. The Exactech Defendants are strictly liable for the defective design of the Device; defective design of the packaging

of the Device; the distribution, marketing, and/or sale of the Device; and the injuries sustained by Plaintiff.

207. By reason of the foregoing acts, omissions and conduct committed by the Exactech Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

208. By reason of the foregoing acts, omissions and conduct committed by the Exactech Defendants, Plaintiff was caused to sustain serious personal injuries, conscious pain and suffering, and physical disability that will require continued and additional medical treatment.

209. The Exactech Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper

Count Four -- Negligent Misrepresentation

210. Plaintiffs re-allege and incorporate by reference all paragraphs above as if fully stated herein.

211. Defendants made statements concerning material facts which Defendants may have believed to be true but which in fact were false, or otherwise omitted material facts, including but not limited to:

a) Representing to the orthopedic community, and Plaintiff's surgeon, prior to implantation into Plaintiff's body, that the GXL performed better than the competitors' Highly Cross Linked Polyethylene;

b) Defendants knew the GXL was failing at a high rate and failed to disclose this information to Plaintiff and/or Plaintiff's surgeon prior to installation of the GXL;

c) Defendants knew that other patients experienced problems with the Device, including but not limited to, osteolysis, loosening of the components, deterioration of the polyethylene, and reports of significant pain, all prior to the installation of the Device in Plaintiff, and failed to disclose such information to Plaintiff and/or Plaintiff's surgeon;

d) Defendants represented to Plaintiff and/or their orthopedic surgeons, prior to the implantation of the GXL Liner within the Device, that the GXL was clinically proven to reduce wear when, in fact, no clinical trials were submitted for approval by the FDA;

e) Defendants misrepresented the success rate of the GXL to Plaintiff's surgeon; and

f) Defendants failed to disclose to Plaintiff's surgeon, prior to the installation of the Device in Plaintiff's body, that they were aware of and/or witnessed revision surgeries in which the Device failed, including becoming loose, causing osteolysis, and causing excessive wear.

g) Representing the GXL to have lower wear propensities than comparable products.

h) Representing that the GXL liner would last for a lifetime

i) Representing the GXL to have better longevity than

comparable products.

j) Failing to inform Plaintiff and the public of the risk of injury after being informed of the increased rate of wear related adverse events with Defendants' other "enhanced" polyethylene products.

k) Failing to inform Plaintiff and the public of any potential risks related to Defendants' increased knowledge of problems associated with the GXL liner until Defendants had already designed and released a marketable replacement for the GXL.

l) Doing all of the above with the intent of selling more hip replacements and creating demand for Defendants' systems by using deceptive or untrue statements of fact about the safety and benefits of the GXL system.

212. Defendants were negligent in making such statements because they knew or should have known the statements were false or omitted material information.

213. In making these statements, Defendants intended or expected that another would rely on the statements.

214. Plaintiff, through Plaintiff's surgeon agents, justifiably relied on the false statements.

215. As a direct and proximate result of the lack of reasonable and adequate instructions or warnings regarding the defects in the GXL, Plaintiff suffered the injuries described above in Section II(M).

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court

deems proper

Count Five – Breach of Express Warranty

216. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

217. Prior to Plaintiff's initial hip surgery, and at all times relevant this action, the Exactech Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

218. The Exactech Defendants expressly warranted the Device was a safe and effective orthopedic devices.

219. The Exactech Defendants promised that the Device had excellent long-term clinical outcomes and that these purportedly "enhanced" GXL liners were "developed to create a robust arthroplasty respecting the need for lower wear, sufficient fracture toughness, and oxidation behavior to provide a lifelong implant for patients."

220. Gary Miller, PhD, Exactech co-founder warranted on behalf of the company that its process "provides a 59% reduction in gravimetric abrasive wear over the clinically successful

standard Exactech."

214. Defendants explicitly claimed that "Connexion GXL enhanced polyethylene acetabular liners provide a low wear rate."

215. Defendants explicitly claimed that "Connexion GXL liners are a result of development programs that are advancing bearing surface technology while focusing on increasing the longevity of total hip prostheses."

216. At the time the Exactech Defendants manufactured, marketed, sold and/or distributed the Device, they knew that the devices were intended for human use, and that Plaintiff was a foreseeable user of the Device.

217. The express warranties represented by the Exactech Defendants were a part of the basis for Plaintiff's use of the Device, and Plaintiff and Plaintiff's surgeon relied on these warranties in deciding to implant the Device.

218. At the time of the making of the express warranties, the Exactech Defendants had knowledge of the purpose for which the Device was to be used and warrantied the same to be in all respects safe, effective and proper for such purpose.

219. The Device does not conform to these express representations as demonstrated by the fact that Plaintiff's implant failed prematurely due to polyethylene wear which necessitated Plaintiff to undergo revision surgery.

220. At the time the Exactech Defendants marketed, sold and/or distributed the Device, the Exactech Defendants expressly warranted that the total hip replacement systems, including all of their component parts, were safe and merchantable for their intended use.

221. Plaintiff and Plaintiff's implanting physician reasonably relied upon the Exactech Defendants' express warranties.

222. Plaintiff used the Devices for their intended purpose, and in a reasonable foreseeable manner.

223. The Devices manufactured and sold by the Exactech Defendants, did not conform to the Exactech Defendants' express representations because the Device caused serious injury to Plaintiff when used as recommended and directed.

224. As a direct and proximate result of the Exactech Defendants' acts and omissions, including breach of express warranty, Plaintiff was implanted with the Device and was caused to sustain serious personal injuries, conscious pain and suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

225. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of

decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

Count Six - Breach of Implied Warranty

226. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

227. Prior to Plaintiff's initial hip surgery, and at all times relevant this action, the Exactech Defendants tested, studied, researched, designed, formulated, manufactured, inspected, labeled, packaged, promoted, advertised, marketed, distributed, and/or sold the Device for implantation into consumers, such as Plaintiff, by orthopedic surgeons in the United States.

228. The Exactech Defendants impliedly warranted, through its marketing, advertising, distributors and sales representatives, that the Device was of merchantable quality, and fit for the ordinary purposes and uses for which it was sold.

229. In fact, the Device was not of merchantable quality nor fit for the ordinary purposes and uses for which it was sold and did not meet the expectations of consumers.

230. The Device manufactured and supplied by the Exactech Defendants was not of merchantable quality and was not fit for the ordinary and/or particular purpose for which it was intended as physicians and patients would expect the components to be properly manufactured, treated to prevent oxidation, and packaged and stored as to avoid premature degradation of component materials.

231. Plaintiff and/or Plaintiff's physician reasonably relied upon the skill and judgment of the Exactech Defendants as to whether the Device was of merchantable quality and safe for its intended and particular use and purpose.

232. Contrary to such implied warranties, the Device was not of merchantable quality or safe for its intended and particular use and purpose, because the Exactech Defendants failed to prevent the components from undergoing increased oxidation and causing patients to experience substantial early polyethylene wear, component loosening and/or other failure causing serious complications including tissue damage, osteolysis, and other injuries as well as the need for revision surgery.

233. As a direct and proximate result of the Exactech Defendants' acts and omissions, including breach of implied warranties, Plaintiff was implanted with a Device and was caused to sustain serious personal injuries, conscious pain and

suffering, physical disability, mental anguish, emotional distress, fear, loss of enjoyment of life, medical expenses, and financial losses.

234. Defendants acted intentionally, recklessly and wantonly without regard for Plaintiff's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

Count Seven – Loss of Consortium and Services

235. Plaintiffs hereby incorporate by reference all previous paragraphs of this Complaint as if fully set forth herein and further allege as follows:

236. At all relevant times, Plaintiff BRIAN CAMP was and is the lawfully wedded husband of Plaintiff CYNTHIA CAMP, and as such, was and is entitled to the services, consortium and society of CYNTHIA CAMP.

237. As a result of the foregoing, Plaintiff BRIAN CAMP was deprived of the services, consortium and society of CYNTHIA CAMP.

238. As a direct, proximate and legal consequence of Defendants' wrongful conduct as described herein, Plaintiff BRIAN CAMP has suffered and will continue to suffer the loss of support,

companionship, service, love, affection, society, intimate relations and other elements of consortium all to the detriment of their marital relationship for which Plaintiff BRIAN CAMP INSDORF is entitled to compensatory and equitable damages in an amount to be proven at trial.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, and severally, as follows:

a. Judgment in favor of Plaintiffs and against all Defendants, for damages in such amounts as may be proven at trial;

b. Compensation for both economic and non-economic losses, including but not limited to medical expenses, loss of earnings, disfigurement, pain and suffering, mental anguish, and emotional distress, in such amounts as may be proven at trial;

c. Punitive and/or exemplary damages in such amounts as may be proven at trial;

d. Attorneys' fees and costs;

e. Interest; and

f. Any and all further relief, that the Court may deem just and proper.

Dated: June 22, 2022

Respectfully Submitted,

WEITZ & LUXENBERG, P.C.
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DEMAND FOR JURY TRIAL

Plaintiffs demand trial by jury.

Dated: July 22, 2022

Respectfully Submitted,

WEITZ & LUXENBERG, P.C.
Attorneys for Plaintiff

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